

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Gregory K. Dahlgren,

Case No. _____

Plaintiff,
v.

DePuy Orthopaedics, Inc., and
Saint-Gobain Corporation,

Defendants.

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

Plaintiff Gregory K. Dahlgren, for his causes of action against the above-named defendants, alleges and states as follows:

PARTIES

1. At all times material herein, plaintiff Gregory K. Dahlgren resided in Minnesota, and currently resides at 9919 Colorado Lane North, Brooklyn Park, Minnesota 55455.

2. Defendant DePuy Orthopaedics, Inc. (“DePuy”) is a corporation organized and existing under the laws of the State of Indiana with its principal place of business in the City of Warsaw, County of Kosciusko, State of Indiana. DePuy is a wholly-owned subsidiary of Johnson & Johnson.

3. Defendant Saint-Gobain Corporation (“Saint-Gobain”) is a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business in the City of Valley Forge, County of Chester, State of Pennsylvania.

4. This Court has original jurisdiction over this civil action pursuant to 28 U.S.C. § 1332. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391.

FACTUAL BACKGROUND

5. At all relevant times, Defendant DePuy created, designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, promoted and distributed in interstate commerce the DePuy Inc. Prodigy Hip System, including a Duraloc cup, an Enduron polyethylene shell, and a DePuy Articul/eze Zirconia Total Hip Ball. A hip ball is also referred to as a femoral head.

6. At all relevant times, Defendant Saint-Gobain created, designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, promoted and distributed in interstate commerce Desmarquest Prozyr zirconia ceramic femoral heads, which Defendant DePuy later sold as the DePuy Articul/eze Zirconia Total Hip Ball.

7. Post-market experience and testing revealed that Desmarquest Prozyr zirconia ceramic femoral heads, including the DePuy Articul/eze Zirconia Total Hip Ball, failed at abnormally high rates, by fracturing inside patients' bodies. Defendant DePuy officially recalled the Articul/eze Zirconia Total Hip Ball, including those bearing catalog number 1365-45-000, on August 13, 2001, in recall number Z-0235-2. The reason given was "Higher than expected failure rate with certain batches of Saint Gobain Desmarquest Zirconia Ceramic Heads."

8. This recall of the DePuy Articul/eze Zirconia Total Hip Ball was sent to hospitals, requesting that they return all of these devices in their possession, so they would not be implanted in any other patients. Presumably, if Defendants had conducted this research prior to marketing, distributing, and selling the Articul/eze Zirconia Total Hip Ball, the same results would have been obtained and the product would never have been allowed on the market.

9. Defendant DePuy widely marketed the Prodigy Hip System, including the Articul/eze Zirconia Total Hip Ball, in the United States. Defendant undertook an advertising

and marketing campaign extolling the virtues of this hip system, claiming that the design of the Prodigy Hip System, including the Articul/eze Zirconia Total Hip Ball, was innovative and would promote stability and long-term implant performance.

10. Notwithstanding the marketing and advertising campaign, these implants were neither safe nor effective for the purpose for which they were marketed due to a high failure rate of the ceramic femoral heads. Medical articles have documented a high failure rate of Saint-Gobain Desmarquest zirconia ceramic heads. For example, a study by Green et al. published in 2003 found up to an 85% failure rate in zirconia heads within 8 years of clinical use. Clarke et al. have reported other studies of zirconia balls finding failure rates of 30% and 70% percent.

11. Defendant Saint-Gobain has acknowledged widespread failures of its zirconia ceramic heads. In May 2003, Saint-Gobain admitted on a company webpage that between late 2000 and May 2003, 317 breakages of hip protheses heads implanted in patients were reported to the company. Early and adequate testing by DePuy and Saint-Gobain would have revealed these deficiencies prior to the time that the Articul/eze Zirconia Total Hip Balls were marketed and sold.

12. On or about August 31, 1999, Gregg Dahlgren underwent total hip arthroplasty for his left hip. The artificial hip placed during the surgery was a DePuy, Inc. Prodigy Hip System with a Duraloc cup, an Enduron polyethylene shell, and a DePuy Articul/eze Zirconia Total Hip Ball. Mr. Dahlgren's medical records reflect he received a DePuy Articul/eze Zirconia Total Hip Ball 28mm in diameter with the catalog number 1365-45-0000. (The same catalog number that DePuy would later recall on August 13, 2001, in recall number Z-0235-2.) The surgery was conducted at St. John's Hospital in Maplewood, Minnesota by Dr. David Palmer. A

representative from Johnson & Johnson, the parent-company of DePuy, was present in the operating room before this surgery.

13. On or about October 18, 2008, Gregg Dahlgren was hiking in the woods near Grand Marais, Minnesota, when he felt a popping and cracking sensation in his left hip. He felt significant pain, but had no choice but to walk approximately 1.5 miles through the woods back to the cabin where he was staying. Once back at the cabin, Mr. Dahlgren sat down to take his hiking boot off, and he felt and heard an additional fracture in his hip. In the following days, Mr. Dahlgren experienced intense pain, loss of appetite, inability to sleep, and was unable to walk without assistance.

14. Mr. Dahlgren was seen by Dr. Palmer as soon as possible, which was on Tuesday, October 21, 2008. At that point, three days after experiencing the popping in his hip, Mr. Dahlgren still had significant pain in his groin and buttock and could not walk unassisted. Dr. Palmer took X-rays of Mr. Dahlgren's hip, and exclaimed, "Oh my," upon reviewing the images of the fractured femoral head. Even to Mr. Dahlgren's untrained eye, it was obvious that the DePuy Articul/eze Zirconia femoral head had fractured into many fragments within his body.

15. Dr. Palmer immediately scheduled Mr. Dahlgren for surgery, and performed revision surgery on Mr. Dahlgren on October 22, 2008 at Lakewood Hospital in Stillwater, Minnesota. His admission statement reported that Mr. Dahlgren was admitted because of a failed ceramic femoral head. The revision operation revealed that while the polyethylene liner, acetabular cup, and femoral stem were in good condition, the DePuy Articul/eze Zirconia head had fractured into many pieces, which were removed from Mr. Dahlgren's tissues during the surgery.

16. As a result of the negligence and other misconduct of the defendants and the defective nature of the Articul/eze Zirconia femoral head, plaintiff Gregory Dahlgren suffered the pain and disability of an early femoral head failure, and was forced to undergo surgery to have the DePuy Articul/eze Zirconia femoral head removed and replaced.

17. Mr. Dahlgren then had to undertake a rehabilitative program to recover from the replacement surgery and restore functioning in the affected hip and leg, including the pain, suffering and disability that accompanied such a recovery. Mr. Dahlgren also missed several weeks of work recovering from this revision surgery, and even when he returned to work, was still tired and in pain.

18. To this day, Mr. Dahlgren continues to experience hip pain and weakness, which limits his activity levels. Mr. Dahlgren will continue to experience the effects of the early failure and replacement of the DePuy Articul/eze Zirconia femoral head, including further weakening of the joint and surrounding tissue as a result of the second surgery, and increased risks of surgery should the current implant fail and need to be replaced.

FIRST CAUSE OF ACTION
**(Strict Liability -- Design, Manufacturing and Warning –
in Tort against DePuy and Saint-Gobain)**

19. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

20. The DePuy Articul/eze Zirconia femoral head manufactured and/or supplied to plaintiff by DePuy and Saint-Gobain was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, the femoral head had not been adequately tested and the risks of serious bodily injury and a lack of effectiveness exceeded the benefits associated with its design or formulation.

21. Alternatively, the DePuy Articul/eze Zirconia femoral head manufactured and/or supplied to plaintiff by DePuy and Saint-Gobain was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, the femoral head was unreasonably dangerous; it was more dangerous than other femoral heads in terms of its danger of fracturing and was not as effective as reasonably expected or advertised.

22. The DePuy Articul/eze Zirconia femoral head manufactured and/or supplied to plaintiff by DePuy and Saint-Gobain was defective due to inadequate warnings or instruction because the manufacturer knew or should have known, through testing or otherwise, that the product created a high risk of bodily injury and serious harm, and a lack of effectiveness, about which DePuy and Saint-Gobain failed to warn.

23. The DePuy Articul/eze Zirconia femoral head manufactured and/or supplied to plaintiff by DePuy and Saint-Gobain was defective due to inadequate post-marketing warnings or instructions because, after the manufacturers knew or should have known of the increased risk of fracture, lack of effectiveness and other risks, they failed to provide adequate warnings to users or purchasers or timely recall the DePuy Articul/eze Zirconia femoral head, and instead continued to sell the DePuy Articul/eze Zirconia femoral head without adequate precautions.

24. As a direct and proximate result of defendant DePuy's and Saint-Gobain's conduct, plaintiff has suffered and will continue to suffer injury, harm, limited mobility and activity levels, and economic loss as alleged herein.

SECOND CAUSE OF ACTION
(Breach of Express Warranty by DePuy and Saint-Gobain)

25. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

26. Defendants DePuy and Saint-Gobain expressly warranted to physicians and consumers, including plaintiff and his physicians, that the DePuy Articul/eze Zirconia femoral head was safe and/or effective and that such safety and/or effectiveness had been shown by scientific study.

27. The DePuy Articul/eze Zirconia femoral head did not conform to these express representations because it was not safe and had a high level of side effects, including is susceptibility to failure by fracturing, and/or other serious health risks suffered by the plaintiff, and/or it was not safe and effective, as was claimed.

28. As a direct and proximate result of the breach of said warranty, plaintiff suffers and will continue to suffer injury, harm, limited mobility and activity levels, and economic loss as alleged herein.

THIRD CAUSE OF ACTION
(Breach of Implied Warranty By DePuy and Saint-Gobain)

29. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

30. At the time DePuy and Saint-Gobain marketed, sold and distributed the DePuy Articul/eze Zirconia femoral head, they knew of the use for which the DePuy Articul/eze Zirconia femoral head was intended and impliedly warranted the product to be of merchantable quality, safe, fit and effective for such use.

31. Plaintiff and/or his physicians reasonably relied upon the skill and judgment of defendants DePuy and Saint-Gobain as to whether the DePuy Articul/eze Zirconia femoral head was of merchantable quality, safe, fit and effective for intended use.

32. Contrary to such implied warranty, the DePuy Articul/eze Zirconia femoral head was not of merchantable quality or safe or fit or effective for its intended use, because the product was and is unreasonably dangerous, unfit and ineffective for the ordinary purposes for which the DePuy Articul/eze Zirconia femoral head was used, namely, for total hip arthroplasty.

33. As a direct and proximate result of the breach of implied warranty, plaintiff suffered and will continue to suffer injury, harm, limited mobility and activity levels, and economic loss as alleged herein.

FOURTH CAUSE OF ACTION
(Negligence of DePuy and Saint-Gobain)

34. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

35. At all times material herein, defendants DePuy and Saint-Gobain had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, sale, withdrawal and recall of the DePuy Articul/eze Zirconia femoral head to insure the safety and/or effectiveness of the product and to insure that the consuming public, including the plaintiff and his physicians and agents, obtained accurate information and instructions for the safe use or non-use of the DePuy Articul/eze Zirconia femoral head.

36. At all times herein, defendants DePuy and Saint-Gobain knew, or in the exercise of reasonable care should have known, that the DePuy Articul/eze Zirconia femoral head was not properly manufactured, compounded, tested, inspected, packaged, labeled, distributed, marketed, examined, maintained, sold and prepared.

37. Each of the following acts and omissions herein alleged was negligently and carelessly performed by defendants DePuy and Saint-Gobain, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to, negligent and careless research and testing of said product, negligent and careless design or formulation of said product, negligent and careless manufacture of said product, negligent and careless inspection of said product, negligent and careless failure to give adequate instructions for the safe use of said product, negligent and careless failure to give adequate warnings to plaintiff, his physicians, and agents and the public in general of the potentially dangerous, defective, unsafe, ineffective and deleterious propensity of said product and of the risks associated with its use and negligent and careless conduct with respect to the marketing of the DePuy Articul/eze Zirconia femoral head to physicians, who then implanted the femoral head implants in patients such as Mr. Dahlgren.

38. As a direct and proximate result of the negligence of defendants DePuy and Saint-Gobain, plaintiff suffered and will continue to suffer injury, harm, limited mobility and activity levels, and economic loss as alleged herein.

FIFTH CAUSE OF ACTION
**(Violation of the False Advertising Act,
the Consumer Fraud Act, the Unlawful Trade Practices Act
and the Uniform Deceptive Trade Practices Act)**

39. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

40. By reason of the conduct as alleged herein, and by inducing plaintiff and his physicians to use the DePuy Articul/eze Zirconia femoral heads through the use of false and/or misleading advertising, representations and statements, defendants violated the provisions of the Minnesota Statutes Sections 325F.67, 325F.69, 325D.13 and 325D.44.38.

41. As a direct and proximate result of defendant's statutory violations, plaintiff was implanted with the DePuy Articul/eze Zirconia femoral head, which would not have occurred had defendants not issued false and/or misleading advertising, representations and statements to induce plaintiff and his physicians to use the product.

42. By reason of such violations and pursuant to Minnesota Statutes Section 8.31, subdivision 3a, Section 325D.44, Section 325F.67, and Sections 325F.68-70, and for the public benefit, plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; together with any and all consequential damages recoverable under the law including, but not limited to, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability and emotional distress.

43. In addition, pursuant to Minnesota Statutes Section 8.31, plaintiff is entitled to recover costs and disbursements, including costs of investigation and reasonable attorneys' fees, and any other equitable relief as deemed by this Court.

DAMAGES

44. As a direct and proximate result of the defendant's acts, Mr. Dahlgren has sustained serious and permanent injuries to his mind and body including, but not limited to, repeated explant surgery. Plaintiff faces additional such injuries in the future as well as increased medical costs. Mr. Dahlgren's injuries are permanent and have caused much pain, mental anguish, suffering, distress and, limited mobility and activity levels, and economic loss. These injuries have decreased plaintiff's ability to enjoy a normal and full life. Plaintiff has also been exposed to future risks of injury caused by the fact that he has been implanted with a DePuy

Articul/eze Zirconia femoral head. Plaintiff has sustained general damages in an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00).

WHEREFORE, plaintiff prays for damages against the defendant, in a sum greater than Seventy-Five Thousand Dollars (\$75,000), together with his costs and disbursements incurred herein, including reasonable attorneys' fees.

JURY DEMAND

Plaintiffs hereby request a trial by jury, pursuant to Rule 38 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Dated: September 2, 2010

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

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